

## Notice of Allowability

Application No.

09/678,652

Examiner

Bradley L. Sisson

Applicant(s)

OSHIDA ET AL.

Art Unit

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to appeal brief of 25 July 2006 and interview of 15 November 2006.
2. ☒ The allowed claim(s) is/are 1-11, 18-29 and 36-49.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|  | 9. <input type="checkbox"/> Other _____.  |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul J. Skwierawski, Reg. No. 32,173, on 15 November 2006.

The application has been amended as follows:

Please replace the title with the following:

Method of Inspecting a DNA Chip

Please amend replace the claim listing with the following:

1. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size D, where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

after sample exposure/coupling, simultaneously irradiating a plurality of the DNA probe cells of said DNA chip with a corresponding plurality of branched laser multi-spot excitation lights through an objective lens so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells;

separating said generated fluorescent lights from said plurality of branched laser multi-spot excitation lights into separate fluorescent lights along separate optical paths; and  
detecting said separate fluorescent lights simultaneously with a plurality of sensors, with each sensor corresponding to each of said DNA probe cells irradiated, so as to catalog positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

2. The method as claimed in Claim 1, wherein said plurality of branched laser multi-spot excitation lights are arranged in a 1-dimensional or 2-dimensional configuration.

3. The method as claimed in Claim 1, comprising:

arranging said plurality of branched laser multi-spot excitation lights irradiated onto said DNA chip on a straight line with a spacing of  $kd$  with reference to a spot diameter  $d$  and an integer  $k$ ; and

scanning a give array line by repeating an operation in sequence  $k$  times, said operation being an operation where, after said irradiation with said plurality of branched laser multi-spot excitation lights has been performed, said plurality of branched laser multi-spot excitation lights are displaced in substantially a direction of said ~~straight~~-array line by substantially  $d$ ; and ~~said irradiation is performed again; and thereby~~

~~executing said inspecting substantially in said straight line direction; and~~

displacing said DNA chip and said objective lens ~~relatively~~-relative to one another at least in a direction substantially perpendicular to said ~~straight~~-array line direction, and repeating the scanning operation to scan another array line; and thereby

inspecting a desired 2-dimensional area on said DNA chip.

4. The method as claimed in Claim 1, comprising providing fluorescent light detection deflecting means within said separate optical paths so that said generated fluorescent lights are synchronized with displacement of said plurality of branched laser multi-spot excitation lights and come onto substantially the same location on light-receiving apertures.

5. The method as claimed in Claim 4, wherein said fluorescent light detection deflecting means includes a wavelength selection beam splitter for permitting said plurality of branched laser multi-spot excitation lights to pass ~~therethrough~~there through and causing said generated fluorescent lights to be reflected.

6. The method as claimed in Claim 1, comprising providing a filter within a fluorescent light detecting optical path isolated from an excitation optical path, said filter permitting only said generated fluorescent lights to pass there-through while light-shielding said plurality of branched laser multi-spot excitation lights.

7. The method as claimed in Claim 1, comprising forming said plurality of branched laser multi-spot excitation lights by using a plurality of laser light-sources.

8. The method as claimed in Claim 7, wherein said plurality of branched laser multi-spot excitation lights are obtained by:

guiding, into optical fibers, lights emitted from said plurality of laser light-sources;  
and causing said lights to be emitted from light-emitting ends of said optical fibers, said light-emitting ends being aligned with M desired pitches.

9. The method as claimed in Claim 1, wherein said plurality of excitation lights include a plurality of different wavelengths, and the method comprising distinguishing ones of the DNA probe cells as different targets on said DNA chip, where a plurality of fluorescent materials responsive to ones of the plurality of different wavelengths are used to distinguish a plurality of different targets.

10. The method as claimed in Claim 9, comprising:  
performing simultaneous irradiation with said plurality of branched laser multi-spot  
excitation lights including said plurality of different wavelengths; and thereby  
distinguishing said different targets on said DNA chip so as to simultaneously detect  
said different targets in accordance with said plurality of fluorescent materials.

11. The method as claimed in Claim 1, comprising:  
directing a second light with an oblique incident angle on an inspection plane of said  
DNA chip;  
detecting a reflection position at which said second light is reflected on said inspection  
plane; and  
controlling a relative distance between said inspection plane and said objective lens in  
accordance with a result of detection of said reflection position.

12.-17. (Canceled)

18. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size  $D$ , where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

branching a laser beam so as to form eight or more beams, said laser beam being emitted from at least one laser light-source;

after sample exposure/coupling, simultaneously irradiating a corresponding eight or more of the DNA probe cells on an inspection plane of a DNA chip with said eight or more beams, respectively, so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells;

separating fluorescent lights emitted from irradiated ones of the DNA probe cells of said DNA chip, from reflected lights of said eight or more beams;

detecting said separated fluorescent lights simultaneously with a plurality of sensors, each sensor corresponding to each irradiated said DNA probe cell, respectively; and

getting information from said DNA chip by cataloging position and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

19. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic

dimensional size D, where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

branching a laser beam into a plurality of beams having substantially the same intensity, said laser beam being emitted from at least one laser light-source;

after sample exposure/coupling, simultaneously projecting said plurality of beams onto a corresponding plurality of the DNA probe cells on an inspection plane of the DNA chip through a projection optical unit, so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells;

detecting, through an imaging optical unit, images of fluorescent lights emitted from irradiated ones of the DNA probe cells of said DNA chip simultaneously with a plurality of sensors, each sensor corresponding to each irradiated said DNA probe cell, respectively, and

getting information from said DNA chip by cataloging position and intensities of detected fluorescent lights concerning a coupled state of the hybridized target DNA on said DNA chip.

20. The method as claimed in Claim 19, wherein said DNA chip is inspected by irradiating said DNA chip with said beams while displacing said DNA chip and said beams relatively relative to one another in a 2-dimensional manner.

21. The method as claimed in Claim 19, wherein said DNA chip is irradiated with said beams arranged in 2-dimensions.

22. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size  $D$ , where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

after sample exposure/coupling, simultaneously irradiating a plurality of the DNA probe cells of said DNA chip with a corresponding plurality of branched laser multi-spot excitation lights so as to emit fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells;

separating said fluorescent lights emitted from ones of the DNA probe cells of said DNA chip, from said plurality of branched laser multi-spot excitation lights:

detecting images of said fluorescent lights simultaneously by use of a plurality of light detecting devices capable of executing a photon counting, each sensor corresponding to each irradiated said DNA probe cell, respectively;

photon-counting, individually, each photon signal obtained from said respective light detecting devices;

storing, individually, data of photon-counted numbers  $N_{pm}$  detected by said respective light detecting devices;

changing positions of said plurality of branched laser multi-spot excitation lights and a position of said DNA chip relative to one another, and repeating said irradiating, separating, detecting, photon-counting and storing operations with respect to another plurality of the DNA probe cells; relatively, so as to store data of said photon-counted numbers from said respective light detecting devices;



~~collecting stored data on said photon counted numbers over desired locations on said DNA chip;~~

constructing a fluorescent light image from stored said ~~collected~~ data; and

deriving information for said DNA chip from stored said ~~collected~~ data, by cataloging positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

23. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size D, where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

after sample exposure/coupling, simultaneously irradiating a plurality of the DNA probe cells of said DNA chip with a sheet-shaped excitation light so as to emit fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells;

separating said fluorescent lights emitted from ones of the DNA probe cells, from said sheet-shaped excitation lights;

detecting images of said fluorescent lights simultaneously by use of a plurality of light detecting devices capable of executing a photon counting, each sensor corresponding to each irradiated said DNA probe cell, respectively;

photon-counting, individually, each photon signal obtained from said respective light detecting devices;

storing, individually, data of photon-counted numbers  $N_{pm}$  detected by said respective light detecting devices;

changing positions of irradiation areas and a position of said DNA chip ~~relatively,~~  
relative to one another, so as to store in sequence data of said photon-counted numbers from said respective light detecting devices; collecting stored data on said photon-counted numbers over desired locations on said DNA chip;

constructing a fluorescent light image from said collected data, and deriving information for said DNA chip from said collected data, by cataloging positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

24. The method as claimed in Claim 22, wherein said branched laser multi-spot excitation lights include 10 or more microscopic spots.

25. The method as claimed in Claim 24, wherein said branched laser multi-spot excitation lights include 50 or more microscopic spots.

26. The method as claimed in Claim 24, wherein said microscopic spots are arranged on a 1-dimensional straight line or a 2-dimensional array.

27. The method as claimed in Claim 22, wherein said branched laser multi-spot excitation lights are colored lights having 2 or more wavelengths.

28. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size  $D$ , where DNA probes are arranged on the DNA chip in a predetermined array, by detecting fluorescent lights generated from a fluorescent material on a DNA sample, comprising:

after sample exposure/coupling, simultaneously irradiating a plurality of the DNA probe cells of said DNA chip with ~~a corresponding plurality of multi-spot excitation lights or~~ a sheet-shaped excitation light so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells, separating said fluorescent lights from said sheet-shaped excitation light, ~~plurality of multi-spot excitation lights irradiated onto said DNA sample, said multi-spot excitation lights including  $M$  microscopic spots, where  $M$  is an integer;~~

detecting fluorescent light images from said fluorescent lights emitted from said DNA chip with the use of a plurality of  $M$  light detecting devices in an average pixel detecting time of  $(300 \mu\text{sec}/M)$  or less, each light detecting device corresponding to each irradiated said DNA probe cell, respectively,

storing, individually, signals obtained from said respective light detecting devices:

changing, ~~relatively,~~ positions of ~~said multi-spot excitation lights or~~ said sheet-shaped excitation light and a position of said DNA chip relative to one another, and repeating said irradiating, detecting and storing operation with respect to another plurality of the DNA probe cells; so as to store said signals in sequence;

~~collecting said stored signals over desired locations on said DNA chip;~~

constructing a fluorescent light image from said ~~collected and~~ stored signals; and

deriving information on said DNA chip from said ~~collected data~~ stored signals, by cataloging positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

29. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size  $D$ , where DNA probes are arranged on the DNA chip in a predetermined array, by detecting fluorescent lights generated from a fluorescent material on a DNA sample, comprising:

after sample exposure/coupling, simultaneously irradiating a plurality of the DNA probe cells of said DNA chip with ~~a corresponding plurality of multi-spot excitation lights or~~ a sheet-shaped excitation light so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells, separating said fluorescent lights from said sheet-shaped excitation light ~~plurality of multi-spot excitation lights~~ irradiated onto said DNA sample, said ~~multi-spot excitation lights~~ including  ~~$M$  microscopic spots having a diameter or focus achieving width which is smaller than  $3\text{ }\mu\text{m}$  and larger than  $0.3\text{ }\mu\text{m}$~~ , said sheet-shaped excitation lights ~~light~~ having a width that is smaller than  $3\text{ }\mu\text{m}$  and larger than  $0.3\text{ }\mu\text{m}$ , ~~where  $M$  is the number of microscopic spots;~~

detecting fluorescent light images emitted from said DNA chip simultaneously with use of a plurality of light detecting devices, each sensor corresponding to each irradiated said DNA probe cell, respectively,

storing, individually, signals obtained from said respective light detecting devices;

changing, ~~relatively,~~ positions of ~~said multi-spot excitation lights or said sheet-shaped~~ excitation light and a position of said DNA chip relative to one another, and repeating said irradiating, detecting and storing operations with respect to another plurality of the DNA probe cells; so as to store said signals in sequence;

~~collecting said stored signals over desired locations on said DNA chip;~~

constructing a fluorescent light image from said collected stored signals; and

deriving information for said DNA chip from said ~~collected data,~~ stored signals, by cataloging positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

30.-35. (Canceled)

36. The method as claimed in Claim 1, wherein said plurality of the DNA probe cells of said DNA chip are simultaneously irradiated with the corresponding plurality of branched laser multi-spot excitation lights for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

37. The method as claimed in Claim 1, wherein each light of said branched laser multi-spot excitation lights having a spot diameter  $d$  that is smaller than the dimensional size  $D$  of a DNA probe cell that it irradiates.

38. The method as claimed in Claim 18, wherein said eight or more of the DNA probe cells are simultaneously irradiated with said eight or more beams, respectively, for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

39. The method as claimed in Claim 18, wherein each beam of said eight or more beams having a spot diameter  $d$  that is smaller than the dimensional size  $D$  of a DNA probe cell that it irradiates.

40. The method as claimed in Claim 19, wherein said plurality of beams are simultaneously projected for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

41. The method as claimed in Claim 19, wherein each beam having a spot diameter  $d$  that is smaller than the dimensional size  $D$  of a DNA probe cell that it irradiates.

42. The method as claimed in Claim 22, wherein the plurality of the DNA probe cells are irradiated for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

43. The method as claimed in Claim 22, wherein each light of said branched laser multi-spot excitation lights having a spot diameter  $d$  that is smaller than the dimensional size  $D$  of a DNA probe cell that it irradiates.

44. The method as claimed in Claim 23, wherein the plurality of the DNA probe cells are simultaneously irradiated for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

45. The method as claimed in Claim 28, wherein the plurality of the DNA probe cells excitation lights are simultaneously irradiated for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

46. The method as claimed in Claim 29, wherein the plurality of the DNA probe cells are simultaneously irradiated for a time  $\Delta t$  that is longer than a fluorescent light attenuation time.

47. The method as claimed in Claim 23, wherein said sheet-shaped excitation lights are colored lights having 2 or more wavelengths.

48. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size D, where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

after sample exposure/coupling, simultaneously irradiating plural DNA probe cells out of said plurality of DNA probe cells of said DNA chip with a corresponding plurality of branched laser multi-spot excitation lights under a condition that each spot of said branched laser multi-spot excitation lights corresponds to a DNA probe cell through an objective lens so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plural DNA probe cells;

separating said generated fluorescent lights from said plurality of branched laser multi-spot excitation lights into separate fluorescent lights along separate optical paths; and

detecting said separate fluorescent lights simultaneously with a plurality of sensors, with each sensor corresponding to each of said DNA probe cells irradiated, so as to catalog positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.

49. A method of inspecting a coupled state of hybridized target DNA on a DNA chip that includes a plurality of DNA probe cells having a DNA probe to which fluorescently labeled target DNA may hybridize, ones of the DNA probe cells being of a microscopic dimensional size D, where DNA probes are arranged on the DNA chip in a predetermined array, comprising:

after sample exposure/coupling, simultaneously irradiating a plurality of the DNA probe cells of said DNA chip with a corresponding plurality of branched laser multi-spot excitation lights under a condition that each spot of the branched laser multi-spot excitation lights corresponds to one DNA probe cell through an objective lens so as to generate fluorescent lights from any fluorescently labeled target DNA hybridized to ones of the DNA probes of the plurality of DNA probe cells;

separating said generated fluorescent lights from said plurality of branched laser multi-spot excitation lights into separate fluorescent lights along separate optical paths;

detecting said separate fluorescent lights simultaneously with a corresponding plurality of sensors under a condition that each separate fluorescent light corresponds to one sensor, so as to catalog positions and intensities of detected fluorescent lights which are representative of a coupled state of the hybridized target DNA on said DNA chip.



The following is an examiner's statement of reasons for allowance: Claims 1-11, 18-29, and 36-49 are allowable over the disclosure of US Patent 6,686,582 B1 (Völcker et al.), the closest prior art of record, for while Völcker et al., do teach using a branched light for the reading of an array of assay signals, they do not teach that the light is that of a branched laser. Further, Völcker et al., are silent to the use of that the light appears in a sheet format. While Völcker et al., at column 3, last paragraph, do teach that "a laser can also be considered for use," they do not set forth an enabling disclosure of how it is to be used in the context of the disclosed methods.

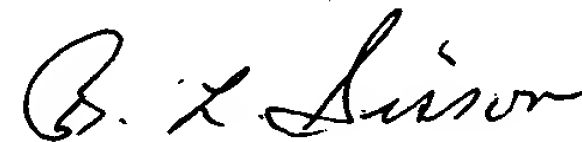
Accordingly, the prior art does not teach or reasonably suggest the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

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